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The effect of oral health education on children's oral hygiene and mothers' knowledge, attitudes, and practices

Submission date
18/10/2024

Recruitment status
No longer recruiting

Registration date
23/10/2024

Overall study status
Completed

Last Edited
04/06/2025

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims:
Good oral health is vital for children's overall well-being, as it affects their ability to eat, speak, and grow properly. In Saudi Arabia, many children suffer from dental issues like tooth decay, with 96% affected by dental caries. Educating young children and their families about oral health can help reduce these problems. This study aims to compare two types of oral health education: conventional methods, such as presentations, and non-conventional methods, like interactive storytelling and games. We want to see which approach better improves children's oral hygiene and mothers' knowledge, attitudes, and practices about their children's dental care.

Who can participate?
Children aged 5-6 years old who are enrolled in kindergartens in Al-Ahsa, Saudi Arabia, along with their mothers, are eligible to participate in this study.

What does the study involve?
Participants will be divided into two groups. One group will receive conventional oral health education through a single presentation, while the other group will receive non-conventional education using interactive methods, including games and storytelling, over several sessions. Both groups of children will have their oral hygiene status assessed by a dentist before and after the program. Mothers will also complete questionnaires to assess their knowledge, attitudes, and practices about their children's oral hygiene before and after the education sessions.

What are the possible benefits and risks of participating?
Children and mothers may benefit from improved oral health knowledge and practices, leading to better dental care for children. There are no significant risks associated with participating, as the educational sessions and dental check-ups are safe and non-invasive.

Where is the study run from?
The study will be conducted in public and private kindergartens across Al-Ahsa, Saudi Arabia.

When is the study starting and how long is it expected to run for?
September 2023 to March 2025.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Hajar Ibrahim Alsuwayi, Hajar.i.alsuwayi@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
The effect of an oral health education program on kindergarten children’s oral hygiene and mothers’ knowledge, attitudes, and practices: a randomized controlled trial

Acronym
OECKAP-RCT

Study objectives
Non-conventional oral health education can improve the oral hygiene status of preschool children, and mothers' oral hygiene knowledge, attitudes, and practices towards their children more than the conventional programs.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 06/03/2024, Research Ethics Committee at King Faisal University (King Faisal University P.O. Box 400, Al-Ahsa, 31982, Saudi Arabia; +966 15899773; ialjreesh@kfu.edu.sa), ref: KFU-REC-2024-MAR-ETHICS2027

Primary study design
Interventional

Study design
Double arm single-blinded randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Improving oral hygiene and health behaviors in kindergarten children and their mothers through oral health education.

Interventions
This study involves a randomized controlled trial designed to assess the effectiveness of an oral health education program on improving oral hygiene in kindergarten children and enhancing mothers' knowledge, attitudes, and practices (KAP) regarding their children's oral health.

The intervention consists of 4 visits to kindergarten schools in Al-Ahsa province, where the children participate in engaging activities, including storytelling, games, and interactive sessions focused on oral health education. The mothers will attend an educational lecture on children's oral hygiene, which will cover essential topics such as proper brushing techniques, dietary influences on oral health, and the importance of regular dental check-ups.

Participants will be randomly assigned to either the intervention group, which receives the oral health education program, or the control group, which receives conventional education on oral health. Randomization will be conducted using a computer-generated randomization sequence to ensure unbiased assignment.

The oral hygiene status of the children will be measured using the Simplified Oral Hygiene Index before and after the program, while the KAP of mothers will be assessed through questionnaires administered before and after the educational lecture.

Intervention Type
Behavioural

Primary outcome(s)
Oral hygiene status is measured using the Simplified Oral Hygiene Index (OHI-S) at baseline and after the completion of the oral health education program

Key secondary outcome(s)
Mothers' knowledge, attitudes, and practices (KAP) regarding children's oral health are measured using a structured questionnaire at baseline before the educational lecture and at follow-up assessment 3 months after the educational lecture

Completion date
30/03/2025

Eligibility

Key inclusion criteria
1. Children aged 5-6 years who are registered in the respective academic year at kindergarten schools in Al-Ahsa.
2. Mothers of preschool children who agree to participate and provide consent.
3. Children and mothers who can attend all educational sessions.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
5 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
1400

Key exclusion criteria
1. Special needs kindergartens.
2. Illiterate mothers.
3. Children with dental anomalies.
4. Children with orthodontic appliances.
5. Children with systemic conditions such as Diabetes mellitus, Hemophilia, Cancer, Craniofacial anomalies, or syndromes.

Date of first enrolment
25/08/2024

Date of final enrolment
25/10/2024

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
The Eighth Kindergarten in Hofuf
Eighth Kindergarten
Al Shehabiyah,
Al Hofuf
Al-Ahsa province
Saudi Arabia
36365

Study participating centre
The Second Kindergarten in Hofuf
Second Kindergarten
6700, 4933,
Al Hofuf and Al Mubarraz
Al-Ahsa province
Saudi Arabia
36361

Study participating centre
The Fifth Kindergarten in Hofuf
Fifth Kindergarten
2796, 9269,
Al Omairiyah,
Al Hufuf and Al Mubarraz
Al-Ahsa province
Saudi Arabia
36362

Study participating centre
Al-Anjal Private Schools
Al-Anjal Private Schools
Next to the train station,
Prince Saud Bin Jalawi Rd,
Al Hofuf
Al-Ahsa province
Saudi Arabia
36361

Study participating centre
Noor Al-Furqan Kindergarten
Noor Al-Furqan Kindergarten
8HMF+GG3, Othman Bin Affan St,
Al Aziziyah, Al Hofuf

Al-Ahsa province
Saudi Arabia
36442

Study participating centre
Happiness Kindergarten
Happiness Kindergarten
87, Al-Rashidiya,
Al-Hofuf and Al-Mubarraz
Al-Ahsa province
Saudi Arabia
36342

Study participating centre
Aljabr Kindergarten
Aljabr Kindergarten
8505 Ain Najm Road,
Al Qadisiyah,
Al Hufuf and Al Mubarraz
Al-Ahsa province
Saudi Arabia
36422

Study participating centre
The third kindergarten in Al-Mubarraz
Third Kindergarten
CH9Q+7MP, Madinatal Mubarraz,
Al Mubarraz
Al-Ahsa province
Saudi Arabia
36341

Study participating centre
Al-Ahsa Girl Charity Private Kindergarten
Al-Ahsa Girl Charity Private Kindergarten
5440, Al Qadisiyah,
Al Qadisiyyah,
Al Hufuf and Al Mubarraz
Al-Ahsa province
Saudi Arabia
36423

Sponsor information

Organisation
King Faisal University

ROR
https://ror.org/00dn43547

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Hajar Alsuwayi, the principal investigator, at Hajar.i.alsuwayi@gmail.com.

The type of data that will be shared includes individual-level data on children's oral hygiene status, as measured by the simplified oral hygiene index, and mothers' responses to questionnaires regarding their knowledge, attitudes, and practices related to their children's dental care.

Data will become available after the study is completed and the results are published, expected by mid-2026. The data will be shared for a duration of five years following publication.

Access to the data will be granted to researchers and healthcare professionals interested in conducting secondary analyses relevant to oral health education and pediatric dentistry. All requests for data will be evaluated on a case-by-case basis.

Consent from participants has been obtained for the use of their anonymized data in research. Data will be anonymized to protect participant identities, and any identifying information will be removed prior to sharing. Ethical considerations have been addressed in accordance with the guidelines set forth by the Research Ethics Committee at King Faisal University.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results	SPSS sav file	04/06/2025	No	No
Dataset		04/06/2025	No	No
Protocol file		23/10/2024	No	No
Statistical Analysis Plan		04/06/2025	No	No